IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Peter Watts and Lisbeth Illum

Serial No.: Continuation of 08/776,470

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For: ANTIVIRAL ICAM-1 COMPOSITIONS IN A BIOADHESIVE FORMULATION FOR NASAL ADMINISTRATION

BOX PATENT APPLICATION
Assistant Commissioner for Patents
Washington, D.C. 20231

PRELIMINARY AMENDMENT

Sir:

Prior to examination of the above-identified patent application, please amend the claims as follows:

In the Specification

Page 1, insert as new paragraph, --This is a continuation of U.S.S.N. U.S. Serial No. 08/776,470 filed March 28, 1997, by Peter Watts and Lisbeth Illum, for "Antiviral ICAM-1 Compositions in a Bioadhesive Formulation for Nasal Administration", now abandoned, which is a 371 of International Application No. PCT/GB95/01735 filed July 24, 1995, in the United Kingdom Receiving office for the Patent Cooperation Treaty, which claims priority to United Kingdom application No. 9414966.3 filed July 26, 1994.--

In the Claims

1. (amended) A drug delivery composition for nasal administration comprising ICAM-1 and a bioadhesive material, wherein the bioadhesive material is in a liquid formulation comprising a polymeric material, wherein the ICAM-1 is present in the liquid formulation in a concentration between about 0.01 and 20% by weight per volume, and wherein the composition delivers to the nasal cavity an antivirally effective amount of ICAM-1.

2. (Amended) The drug delivery composition according to claim 1 wherein the bioadhesive material is a chitosan solution.

3. (Amended) The drug delivery composition according to claim 2 wherein the chitosan is in the solution in a concentration in the range of 0.2 - 2.0% w/v.

4. (Amended) The [A] drug delivery composition according to claim 2 [or 3] wherein the ICAM-1 is present in the chitosan solution in a concentration in the range of 0.2 to 5% w/v.

5. (Amended) A drug delivery composition for nasal administration comprising ICAM-1 and a [according to claim 1 wherein the] bioadhesive material in a dry powder formulation, wherein the bioadhesive material is a plurality of microspheres made from a material selected from the group consisting of starch, chitosan, gelatin, hyaluronic acid, alginate, and gellan, wherein the ICAM-1 content of the formulation is between about 0.1 and 50% by weight, and wherein the composition delivers to the nasal cavity an antivirally effective amount of ICAM-1.

Please cancel claim 6.

7. (Amended) The [A] drug delivery composition according to claim 5 [or 6] wherein the ICAM-1 is present in an amount of 1% to 20% w/w of the microspheres.

Please cancel claim 8.

9. (Amended) The [A] drug delivery composition according to claim 1 wherein the polymeric material is selected from the group consisting of gellan gum, alginate, welan, xanthan, [or] and rhamsan.

10. (Amended) The [A] drug delivery composition according to claim [8 or 9] 1 wherein the polymeric material is provided in a concentration of 0.1% to 5% w/v.

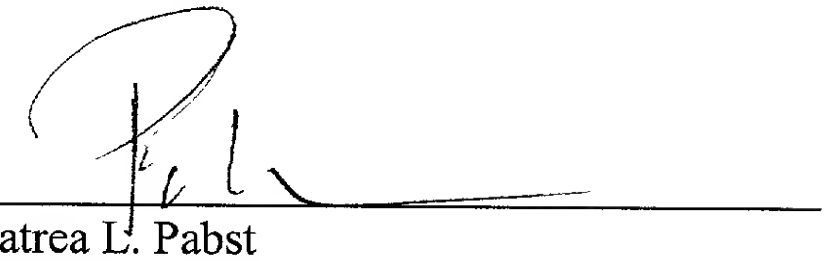
11. (Amended) [A] The drug delivery composition according to [any one of claims 9-10] claim 8 wherein the ICAM-1 is present in the formulation in an amount of 0.2% to 5% w/v.

12. (Amended) A method of delivering ICAM-1 to the nasal cavity to increase its effectiveness therein comprising

administering the ICAM-1 in a drug delivery composition additionally comprising a bioadhesive material, wherein the bioadhesive material is in a liquid formulation comprising a polymeric material or is in a dry powder formulation comprising a plurality of microspheres made from a material selected from the group consisting of starch, chitosan, gelatin, hyaluronic acid, alginate, and gellan, and wherein the composition delivers to the nasal cavity an antivirally effective amount of ICAM-1.

Favorable consideration is earnestly solicited.

Respectfully submitted,



Patrea L. Pabst
Reg. No. 31,284

Date: May 3, 2001
HOLLAND & KNIGHT LLP
One Atlantic Center
1201 West Peachtree Street, N.E.
Suite 2000
Atlanta, Georgia 30309-3400
(404) 817-8473
(404) 881-0471

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